IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	**:**	
v.	**:**	**CRIMINAL NO. 23-cr-89**
	:	
PETER N. STOLL, III		

GOVERNMENT'S SENTENCING MEMORANDUM

Defendant Peter N. Stoll, III, counterfeited two Food and Drug Administration ("FDA") letters that led to hundreds of unapproved medical devices being sent to medical facilities across the country. Stoll's deception was not an isolated incident. For months, as a regulatory associate for a medical device manufacturer, Stoll repeatedly concealed from his employer that he had failed to file approval submissions with FDA. To save his job, he created the two fake letters which resulted in adulterated and misbranded medical devices being distributed and used throughout the country. In so doing, Stoll created a direct threat to Americans' health and safety. His behavior merits a within-guidelines sentence.

The defendant's misconduct is striking in both its simplicity and brazenness. He falsified two letters from FDA, months apart, claiming that the agency had cleared two medical devices for distribution and use throughout the United States. Manufacturing these counterfeit government letters, however, were not lone indiscretions or momentary lapses in judgment. They were the culmination of a months-long pattern of lying and obfuscation. He lied to his co-workers and supervisors for months about his progress filing submissions with FDA. He created fake questions and correspondence from FDA and presented them to his co-workers for ostensible resolution.

When his coworkers began inquiring further, Stoll manufactured the false letters on FDA letterhead, falsely stating that FDA had cleared the devices.

Allowing medical devices into interstate commerce that have not been cleared by FDA posed significant risks to the health of patients exposed to the devices. The first device, the ELAN-4 Air Drill ("ELAN-4"), is a high-speed drill used to cut through bone in spinal, ear nose and throat, neuro and maxillofacial surgical procedures. Simply put, because of Stoll's conduct, brain and spinal surgeries may have been conducted with drills that FDA did not first determine were safe and effective to use. The other device, the SterilContainer JS Series 2 ("SterilContainer"), is a metal container used to sterilize reusable surgical instruments following procedures to reduce risk of contamination and infection. FDA did not determine the device's safety or effectiveness prior to it being distributed to surgical facilities.

In addition to the real-world risk of harm that Stoll's conduct caused, there was also a pecuniary loss that the Pre-Sentence Report ("PSR") correctly determined. If anything, the PSR likely undercounts the loss amount because it does not take into account sales of the ELAN-4 drills that were sent to providers under consignment. Relatedly, the defendant objected to the loss amount in the draft PSR because his employer refunded purchasers of the devices or was able to resell the devices after FDA had cleared the 510(k) for each device. This argument fails because the defendant should not get credit for loss mitigation done by a third party *after* it had detected and reported his fraud.

The government explains below its view of the proper consideration in this case of the advisory guideline range and of the Section 3553(a) factors, which support a within-guideline sentence in this case.

I. BACKGROUND

Aesculap A.G. ("Aesculap") hired the defendant in 2015 as a Regulatory Affairs Specialist. His responsibilities included assisting the company in filing 510(k) submissions to FDA for medical devices manufactured by Aesculap.[1] Stoll was responsible for filing and shepherding Aesculap's 510(k) submissions for the ELAN-4 and SterilContainer. Instead of making the 510(k) submissions for either device, Stoll forged two letters on FDA letterhead claiming the agency had cleared the devices and they could therefore lawfully be shipped in interstate commerce. As a direct result of Defendant Stoll's deceitful actions, hundreds of misbranded and adulterated medical devices were unlawfully distributed in interstate commerce.

A. *The ELAN-4 Submission*

As a Regulatory Affairs Specialist for Aesculap, Stoll had access to, and was familiar with, legitimate 510(k) clearance letters from FDA. On or about January 10, 2017, Stoll copied such a legitimate 510(k) clearance letter and manipulated it on his company-issued computer by changing the letter's date and the device name to make it appear that FDA had cleared the ELAN-4, a surgical drill, as safe and effective. In fact, FDA had not done so. Stoll circulated this false letter internally at Aesculap and told Aesculap employees that FDA had cleared the device to be marketed in interstate commerce. Laboring under the false impression created by Defendant Stoll,

1 In order to be legally marketed in the United States, most medical devices must first be reviewed by FDA. 21 U.S.C. § 360 *et seq.* Most medical devices are brought to market through what is called the 510(k) pathway. This path involves submitting a "510(k) notification" to FDA demonstrating that the device is substantially equivalent to a marketed device already lawfully on the market. 21 U.S.C. § 360c(C)(2)(C)(ii)(II). FDA then reviews that filing to determine whether the new device is in fact substantially equivalent to the predicate device such that there is a reasonable assurance of the device's safety and efficacy for its intended use. FDA either clears, denies, or requests additional information within 90 days of filing. *Id.* FDA clearance means that the submitted device is substantially equivalent and thus may be marketed in the U.S. Until the submitter receives an order from FDA declaring the device to be substantially equivalent, the submitter may not lawfully market the device.

Aesculap shipped ELAN-4 devices to medical providers throughout the United States for use on human patients.

Manufacturing the bogus FDA clearance was Stoll's final act in a months-long cover-up designed to conceal the fact that he was not fulfilling his job responsibilities. Defendant's own contemporaneous emails show that for months prior to circulating his counterfeit FDA letter, he repeatedly concealed from his employer that he had failed to submit any 510(k) paperwork for the ELAN-4 to FDA. As early as March 6, 2016, the defendant told an employee at B. Braun, Aesculap's German-based parent company, that he was "almost done" with the 510(k) submission for the ELAN-4. Soon thereafter, Stoll falsely told that same employee that he had sent the 510(k) submission to the FDA.

For months, when Aesculap employees questioned him about the status of the regulatory filing, Stoll maintained that he had submitted it. Moreover, Stoll repeatedly and falsely told others at Aesculap that FDA had responded with questions to him about the ELAN-4 510(k) submission and that he was working on providing answers to the agency. Of course, the truth was FDA had no questions about a 510(k) submission that it had never received. After numerous back-and-forth emails between Stoll and others at Aesculap, on or about October 6, 2016, Stoll repurposed a previous set of FDA questions that Aesculap had previously received about a different device and sent them to another Aesculap employee falsely representing them as questions FDA had about the supposed ELAN-4 510(k) submission.

Finally, on or about January 3, 2017, Stoll told his coworkers that Aesculap expected FDA clearance "sometime tomorrow or the following day when our FDA reviewer returns to the office." Instead of confessing that he had not filed a 510(k) for the ELAN-4 and had lied about it for months, Stoll took it upon himself to fabricate a counterfeit 510(k) clearance letter from the FDA

falsely stating that FDA had cleared the ELAN-4 to deceive his superiors.

Stoll created this letter by electronically manipulating the digital copy of a previous 510(k) clearance letter from FDA. On his company-issued computer, Stoll engineered the letter to appear that FDA had cleared the 510(k) for the ELAN-4 by changing the letter's date and the 510(k) reference number ("K Number") to match a number that Stoll had previously used. He dated the letter January 5, 2017. The bottom of the letter contained the signature block of an actual FDA official, who had not signed this letter.

On or about January 10, 2017, Stoll emailed the letter to several Aesculap employees, including several in Aesculap management, writing that "[t]he ELAN-4 Air Motor System has been cleared for marketing by the FDA . . . . We received the substantial Equivalence determination on Monday, January 9th." None of this was true.

B. *The SterilContainer JS Series 2*

Like the ELAN-4, Stoll created and circulated false documents intended to make others at Aesculap believe that FDA had also cleared Aesculap's SterilContainer. Over the course of nearly a year, Stoll lied to his coworkers, telling them that he had filed a 510(k) submission for the SterilContainer when he had not. When his supervisors began to probe further about the 510(k) status, Stoll once again created a bogus letter purporting to be from FDA that stated the agency had cleared the device to be distributed in interstate commerce.

Beginning on or about May 13, 2016, Stoll wrote to a B. Braun employee in Germany that he expected FDA clearance for the SterilContainer in three months. However, on or about August 10, 2016, Stoll later claimed that because FDA had questions about the 510(k) submission, clearance would be delayed. The truth was that neither Stoll, nor anyone else at Aesculap, had submitted a 510(k) for the SterilContainer.

Later, on or about May 4, 2017, Stoll informed his supervisor and others in an email that "the Aesculap SterilContainer S2 (JS Series) has been cleared for marketing by the FDA . . . . We received the Substantial Equivalence determination on Monday, January 9th." He included two attachments to his email: (1) a counterfeit acknowledgment letter from an FDA employee dated May 1, 2017, addressed to Stoll stating that FDA had *received* the 510(k) submission and (2) Indications for Use form related to the SterilContainer.

Like before, Stoll's email announcing FDA clearance was false. Like before, he fabricated the FDA letter that he circulated to Aesculap staff. And, like before, he never submitted *any* documentation to FDA. In a tell-tale sign that Stoll was retracing his prior ELAN-4 deceit, he mistakenly wrote that the FDA cleared the device on January 9, which was the same clearance date that he had used in his bogus FDA letter for the ELAN-4. Once Stoll realized his mistake in reusing the same date for both of his lies, he attempted to cover it up by sending yet another false email to the Aesculap group, claiming "[t]he date we received Substantial Equivalence determination was actually May 1, and not January 9."

C. *Stoll Created False Documents to Deceive His Employer*

Once Aesculap began to uncover that Stoll had not properly filed the 510(k)s for the two devices, he doubled down on his scheme and created more bogus FDA letters in an effort to mitigate his misconduct. On or about August 23, 2017, Aesculap management confronted Stoll about the absence of the 510(k) clearance letter from FDA for the ELAN-4 in its physical and electronic records. Rather than come completely clean with his bosses and tell them that he had been lying to them for months, Stoll quickly counterfeited two additional FDA letters in order to attenuate the seriousness of his misconduct: the first, a letter dated March 24, 2017, from FDA to Stoll notifying him that Aesculap had failed to file a "complete response" to the ELAN-4 510(k)

submission and therefore FDA considered the 510(k) submission withdrawn; and the second, a nearly identical letter dated May 30, 2017 addressed to the Defendant, notifying him that FDA considered the SterilContainer 510(k) withdrawn for the same reason. Both of these letters were manipulated copies of a legitimate May 2, 2016 letter from FDA to an Aesculap employee where the FDA considered a submission withdrawn. The metadata of both documents reveal that Stoll edited the ELAN-4 letter on or about August 23, 2017, at 1:15 p.m., mere minutes after his managers confronted him.

D. *Charge and Plea*

On March 6, 2023, the Government charged Defendant Stoll by Information to one count of causing the introduction of misbranded and adulterated medical devices into interstate commerce with the intent to defraud and mislead. 21 U.S.C. §§331(a), 333(a)(2). On July 20, 2023, the defendant pleaded guilty to the Information. The Court has scheduled sentencing for November 7, 2023.

II. SENTENCING CALCULATION

A. Statutory Maximum Sentence.

The maximum sentence of imprisonment that may be imposed on the defendant is three years. The maximum fine is $250,000. There is a mandatory $100 special assessment. 21 U.S.C. § 331(a). Statutorily, the defendant is eligible for not less than one nor more than five years' probation because the offense is a Class E Felony; however, because the applicable guideline range is in Zone C of the Sentencing Table, the defendant is ineligible for probation. 18 U.S.C. § 3561(c)(1).

B. Sentencing Guidelines Calculation.

The Probation Office correctly calculated the defendant's advisory guideline range as follows: Base Level of 6 with a fraud loss amount of $122,835 resulting in an 8-point increase to the offense level. The defendant is entitled to a 2-point reduction for acceptance of responsibility resulting in a total offense level of 12. As of November 1, 2023, the Defendant is entitled a further 2-point reduction as a qualified first-time offender under the new Zero-Point Offender Adjustment U.S.S.G. § 4C1.1 resulting a total offense level of 10. Because the Defendant's criminal history is 0, his advisory guidelines range is 6 to 12 months incarceration.

III. ANALYSIS

A thorough consideration of the sentencing factors set forth in 18 U.S.C. 3553(a) results in a sentence within the advisory guideline range of 6 to 12 months.

The Supreme Court has declared: "As a matter of administration and to secure nationwide consistency, the Guidelines should be the starting point and the initial benchmark." *Gall v. United States*, 552 U.S. 38, 49 (2007). "These requirements mean that '[i]n the usual sentencing, … the judge will use the Guidelines range as the starting point in the analysis and impose a sentence within the range." *Peugh v. United States*, 133 S. Ct. 2072, 2083 (2013) (quoting *Freeman v. United States*, 131 S. Ct. 2685, 2692 (2011) (plurality opinion); ellipsis in original). "Common sense indicates that in general, this system will steer district courts to more within-Guidelines sentences." *Peugh*, 133 S. Ct. at 2084. "The federal system adopts procedural measures intended to make the Guidelines the lodestone of sentencing." *Id.*

In addition, this Court must also consider all the sentencing considerations set forth in Section 3553(a). Those factors include: (1) the nature and circumstances of the offense and the history and characteristics of the defendant; (2) the need for the sentence imposed to reflect the

seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense; (3) the need to afford adequate deterrence to criminal conduct, and to protect the public from further crimes of the defendant; (4) the need to provide the defendant with educational or vocational training, medical care, or other correctional treatment in the most effective manner; (5) the guidelines and policy statements issued by the Sentencing Commission; (6) the need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct; and (7) the need to provide restitution to any victims of the offense. 18 U.S.C. § 3553(a).

A. Consideration of the 3553(a) Factors.

The defendant's fraud was egregious and endangered unsuspecting patients. Anyone who underwent a neurosurgical procedure where an ELAN-4 was used was put at risk of serious injury. Anyone who had a medical instrument that was "sanitized" by a SterilContainer was put at risk of possible infection or contamination. Congress enacted a comprehensive regulatory scheme to ensure that only devices that had first demonstrated to FDA were safe and effective would find their way into the hands of health professionals or patients. Defendant Stoll intentionally thwarted this process and created a risk to public health in favor of his own personal self-interest.

As detailed above, the defendant did not do this as a one-off a mistake. He lied to others for months. At any point over the seven-month period between May 2016, when the Defendant falsely claimed that the 510(k) for the ELAN-4 had been submitted, until he created the fraudulent letter in January 2017, the Defendant could have come forward and admitted to his co-workers that he had failed to file the 510(k). Likewise, he opted to conceal the truth for the nearly one-year process for the SterilContainer. His actions along the way were brazen and calculated, weaving a more complicated web of lies with each step, even inventing questions that he claimed were from

FDA multiple times to avoid detection. When he was finally caught by his employer, rather than come clean, he simply counterfeited again.

If the defendant had come forward and admitted that he had not filed a submission for either device, he might have lost his job, but would not be guilty of a crime. His own hubris has led him here. He thought nothing of fraudulently copying a letter from FDA that he knew would result in surgical drills and sterilization devices being used on patients that had not first been determined to be safe or effective. In short, Stoll selfishly decided avoiding his own embarrassment was more important than the health and safety of the American public. That choice must not be condoned by this Court.

The defendant's background makes this crime perplexing, but not deserving of a below guidelines sentence. As the PSR details, the defendant was raised in a loving home with two caring parents and two younger brothers, all of whom continue to provide him exceptional support today. After excelling in school and earning a Bachelor's degree from an Ivy League institution, he obtained an important job with a leading medical device manufacturer. After Aesculap fired him, he landed softly at a desk in his family's business. That he was privileged to enjoy these advantages in life in no way should be seen as factors in favor of a sentence below the guidelines range.

Defendant's misconduct was serious and requires a sentence that establishes a general deterrent, especially in the context of a regulatory system that depends heavily on trust and transparency from drug and device manufacturers to ensure public safety. FDA relies on the representations made in every 510(k) submission to be truthful and accurate and that most manufacturers intend to comply with the law. Problems related to medical devices can have serious consequences for consumers, including injuries and even death. A guidelines sentence is necessary to make clear that such conduct can never be tolerated in order to protect public health.

In addition, adherence to the recommended guideline range is the only course for assuring that the defendant's sentence is consistent with those imposed nationwide on similarly situated offenders, and thus complying with Section 3553(a)(6) and avoiding undue disparity.

There is no need in this case to adjust the sentence in order "to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner . . . ." § 3553(a)(2)(D). Also, restitution is not an issue in this case. § 3553(a)(7).

Therefore, in sum, all of the appropriate considerations of sentencing favor the imposition in this case of a within-guideline sentence. As noted, the Sentencing Guidelines present "the lodestone of sentencing," *Peugh*, 133 S. Ct. at 2084, and that guide is once again persuasive in this case.

B. The Loss Amount is Appropriately Calculated

The Government's loss calculation of $122,835 is appropriate and even discounts the seriousness of the offense.

The defendant argues that the loss amount should effectively be zero because (1) all purchasers of the misbranded devices were refunded through the recall process or (2) Aesculap could resell the misbranded devices after receiving 510(k) approval. In essence, defendant wishes to get credit for being caught. The sentencing guidelines afford a convicted defendant credit against the loss amount for the "fair market value of the property returned . . . *by the defendant* . . . to the victim *before* the offense was detected." U.S.S.G. § 2B1.1(E) (emphasis added). The time of detection is the earlier of "(I) the time the offense was discovered by a victim or government agency; or (II) the time the defendant knew or reasonably should have known that the offense was detected or about to be detected by a victim or government agency." *Id.*

As an initial matter, the guidelines state that the loss amount reduction is for property

returned *by the defendant*, not just anybody. Here, Defendant Stoll did not return anything. Nor was anything returned on his behalf. Instead, he argues that because purchasers of the medical devices were eventually refunded by *Aesculap* following the recall, there is no loss that can be attributed to his conduct. Or, in the alternative, Stoll argues that Aesculap suffered no loss because the devices were resalable following the subsequent 510(k) approval. These returns do not inure to defendant's benefit under the loss calculation because it was Aesculap (not Stoll) who reimbursed purchasers; Stoll provided nothing to Aesculap or its customers.

Secondly, any restitution following the discovery of the fraud is moot for loss amount calculations at sentencing. *See United States v. Eisenhart*, 43 App'x 500, 503 (3d Cir. 2002) ("restitution payments that are tendered after a fraud is detected ordinarily do not reduce the applicable offense level.") (citing *United States v. Shaffer*, 35 F.3d 110, 115 (3d Cir. 1994)). Here, no property was returned to any victim before Aesculap discovered the fraud on or about August 23, 2017. The purchasers of the devices may have been made whole by Aesculap via the recall procedure, it was only *after* Stoll's fraud had been detected by Aesculap and it informed FDA. Therefore, the Defendant is not entitled to the loss amount credit he seeks.

Third, gross sales is an appropriate metric to measure the loss amount for sentencing purposes as it is the actual loss suffered. The guidelines commentary explains that where, as here, articles requiring "regulatory approval by a government agency was required but not obtained, or was obtained by fraud, loss shall include the amount paid for the property, services or goods transferred, rendered, or misrepresented, with no credit provided for the value of those items or services." U.S.S.G. § 2B1.1(F)(v). Using gross sales as a measure does not expand the ordinary definition of "loss" as described in *United States v. Banks*, 55 F.4th 246 (3d Cir. 2022), where the issue was use of intended loss rather than actual loss. Here, the gross sales is an accurate measure

of actual loss; it is that which purchasers paid for the adulterated and misbranded devices that the defendant caused to be introduced into interstate commerce.

Lastly, the loss amount attributed to the Defendant for sales made in connection with ELAN-4 are solely the blades and burrs that Aesculap recalled, not the drills that were sent into interstate commerce because Aesculap loaned the drills to medical providers and sold the drill parts. As such, if the PSR loss amount is inaccurate, it is because the true loss amount is much higher.

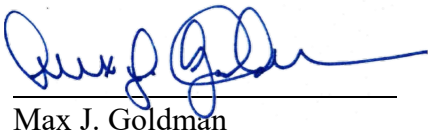
For all of these reasons, the advisory guideline range appropriately captures the seriousness of Defendant's conduct. Accordingly, the government respectfully recommends a sentence within the range of 6-12 months imprisonment.

IV. CONCLUSION

For these reasons, the government recommends that the Court impose a sentence within the advisory guideline range.

Respectfully submitted,

JACQUELINE C. ROMERO
Acting United States Attorney



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CERTIFICATE OF SERVICE

I hereby certify that this Sentencing Memorandum has been served on the Filing User identified below through the Electronic Case Filing (ECF) system:

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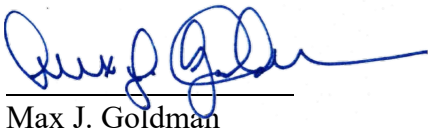

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DATED: October 31, 2023.